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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/320,156 05/26/99 ROSENBLUM

M D5425CIP2

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HM22/0913

EXAMINER

ART UNIT

PAPER NUMBER

1642  
DATE MAILED:

17  
09/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/320,156

Applicant(s)

Rosenblum et al

Examiner

Karen Canella

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) 1-14, 20, and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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***Response to Arguments***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 1-21 are pending. Claims 1-14, 20 and 21, remain withdrawn from consideration. Claims 15-19 are under consideration.

***Claim Rejections Withdrawn***

3. The rejection of claim 18 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to make/use the invention, is withdrawn in light of applicant fulfilment of the deposit requirements.

***Claim Rejections Maintained***

4. The rejection of claim 15 and 19 under 35 U.S.C. 103(a), as being unpatentable over Bacus et al (USP 5,514,554, effective filing date 9/27/91) in view of Rosenblum et al (Cancer Communications, 1991) and Hudziak et al (Molecular and Cellular Biology, 1989), is maintained for reasons of record..
5. The rejection of claims 15, 16, 17 and 19 under 35 U.S.C. 103(a), as being unpatentable over Wels et al (USP 5,571,894, effective filing date 7/15/91) in view of Hoogenboom et al (Biochimica et Biophysica Acta, 1991, Vol. 4, pp. 345-354 and Hudziak et al (Molecular and Cellular Biology, 1989), is maintained for reasons of record.

Applicant argues that the combination of cited references do not anticipate the current invention as it would not be possible to anticipate that the conjugation with tumor necrosis factor would disrupt the biological activity of the tumor necrosis factor, or the binding ability of the antibody. Applicant further argues that it would require non-routine experimentation , beyond

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that which is obvious to one of skill in the art to determine if the anti-Her-2/erbB2 -tumor necrosis factor conjugate would exhibit the same effect as the separate administration of each component. This has been considered but not found persuasive. Bacus et al teaches a method of chemical conjugation (SPDP) linking anti-erbB2 with ricin, preserving the biological function of ricin and the binding ability of the anti-erbB2 antibody. Rosenblum et al teaches the same method of chemical conjugation (SPDP) to link tumor necrosis factor to an antibody which binds an unrelated protein, wherein the biological activity of the conjugated tumor necrosis factor was preserved along with the binding ability of the antibody. Thus, the prior art teaches the chemical conjugation of tumor necrosis factor to an antibody by SPDP chemistry does not alter the activity of the tumor necrosis factor or the antibody. Rosenblum et al also teaches the improvement of directed targeting of tumor cells by the conjugation of the tumor necrosis factor to an antibody which binds the tumor cell. Hudziak et al teaches the motivation to combine an antibody to Her-2 and necrosis factor in the treatment of tumor cells.

#### *New Claim Rejection*

6. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Wels et al (USP 5,571,894, effective filing date 7/15/91) in view of Hoogenboom et al (Biochimica et Biophysica Acta, 1991, Vol. 4, pp. 345-354 and Hudziak et al (Molecular and Cellular Biology, 1989), is maintained for reasons of record given paragraph 5 of the Office action of Paper No. 11.

#### *Conclusion*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

September 9, 2001

  
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